Adopt 17 Cal. Code of Regs. section 100010 to read:

§ 100010. Scope of Chapter 2 – Stem Cell Research.

The standards set forth in this chapter apply to all institutions, as defined by Title 17, California Code of Regulations, section 100020, subdivision (g), performing research, as defined in Title 17, California Code of Regulations, section 100020, subdivision (d), funded by the California Institute for Regenerative Medicine (CIRM) as authorized by Article XXXV of the California Constitution.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100020 to read:

§ 100020. Definitions.

As used in this chapter:

(a) "Acceptably derived" means derived in accordance with the requirements of 17 Cal. Code Regs, sections 100080 and 100090.

(b) "CIRM" means the California Institute for Regenerative Medicine.

(c) ~~"Covered stem cell line" means a culture-derived, human stem cell population that is capable of: 1) sustained propagation in culture; 2) differentiation along multiple cell lineages; and 3) self-renewing to produce daughter cells with equivalent developmental potential. This definition includes both embryonic and non-embryonic human stem cell lines regardless of the tissue of origin."~~ "Covered stem cell line" means a culture-derived, human pluripotent stem cell population that is capable of: 1) sustained propagation in culture; a~~A~~nd~~ND~~ (2) self-renewal~~ing~~ to produce daughter cells with equivalent developmental potential. This definition includes both embryonic and non-embryonic human stem cell lines regardless of the tissue of origin. "Pluripotent" means capable of differentiation into mesoderm, ectoderm, and endoderm.

(d) "Funded research" means research supported in whole or part by funds authorized by article XXXV of the California Constitution. For the purpose of this chapter, training activities supported by such funds shall be considered funded research.

(e) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

(f) "Institution" means any public or private entity or agency (including federal, state, local or other agencies).

(g) "Institutional Review Board" ("IRB") is an entity established in accordance with Title 45, Code of Federal Regulations, section 46.107, revised June 23, 2005.

(h) "Permissible Expenses" means necessary and reasonable costs directly incurred as a result of donation or participation in research activities. Permissible expenses may include but are not limited to costs associated with travel, housing, child care, medical care, health insurance and actual lost wages.

(i) "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of these regulations, whether or not they are conducted or supported under a program which is considered research for other purposes.

(j) "Somatic Cell Nuclear Transfer" ("SCNT") means the transfer of a somatic cell nucleus ~~from a somatic cell~~ into an oocyte. ~~from which the nucleus has been removed.~~ ~~(ref 2-71 WC025)~~

(k) "Stem Cell Research Oversight Committee" (SCRO committee) means a committee established in accordance with 17 Cal. Code Regs. section 100060.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, 125292.10, subds. (p)(q), Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100030 to read:

§ 100030. Activities Not Eligible for CIRM Funding.

The following activities are not eligible for CIRM funding:

(a) Human reproductive cloning, as defined in California Health and Safety Code Section 125292.10. subdivision (k), or reproductive uses of SCNT prohibited by article XXXV section 3 of the California Constitution.

(b) The culture in vitro of (i) any intact human embryo or (ii) any product of SCNT, parthenogenesis or androgenesis, after the appearance of the primitive streak or after 12 days whichever is earlier. The 12 day prohibition does not count any time during which the embryos and/or cells have been stored frozen.

(c) The introduction of stem cells from a covered stem cell line into nonhuman primate embryos.

(d) The introduction of any stem cells, whether human or nonhuman, into human embryos.

(e) Breeding any animal into which stem cells from a covered stem cell line have been introduced.

(f) The transfer to a uterus of a genetically modified human embryo.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, 125292.10, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100040 to read:

§ 100040. Institutional Assurance of Compliance.

(a) All research institutions shall be responsible for providing written assurance satisfactory to CIRM that CIRM-funded research complies with the requirements set forth in this chapter.

(b) Each institution shall:

(1) Ensure that ~~T~~the chancellor, chief executive officer or person with plenary authority ~~shall d~~Designates an institutional official responsible for oversight of and documentation of compliance for CIRM-funded research;

(2) Designate one or more SCRO committee(s) established in accordance with the requirements of 17 Cal. Code Regs section 100060;

(3) Designate one or more IRB(s);

(4) Ensure that clinical personnel who have a conscientious objection not be required to participate in providing donor information or securing donor consent for research use of gametes or embryos. That privilege shall not extend to the care of a donor or recipient.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100050 to read:

§ 100050. Compliance.

Grantees must report promptly to CIRM any failure to comply with the terms and conditions of an award. Depending on the severity and duration of the non-compliance, CIRM actions may include, but are not limited to, the following:

(a) Temporary withholding of payment;

(b) Placing special conditions on awards;

(c) Conversion to a reimbursement payment method;

(d) Precluding the grantee (principal investigator (PI) or grantee organization, as appropriate) from obtaining future awards for a specified period;

(e) Debarment from receipt of further CIRM funds;

(f) Recovery of previously awarded funds;

(g) Civil action, including referring the matter to the Office of the Attorney General of the State of California for investigation and enforcement;

(h) Other available legal remedies.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections125290.40, 124290.55, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100060 to read:

§ 100060. SCRO Committee Membership and Function.

(a) A SCRO committee shall be comprised of persons with expertise in, including but not limited to, developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical issues in stem cell research. A SCRO committee shall include at least one non-scientist member ~~representative~~ of the public who is not employed by, appointed to, or remunerated by the relevant research institution. Any member of a SCRO committee member may be reimbursed for permissible expenses, as defined in Title 17, California Code of Regulations, section 100020, subdivision (h). In addition, a~~n~~ SCRO committee shall include at least one patient advocate. ~~No SCRO committee member may have a financial conflict of interest in the research under review~~. No SCRO committee may have a member participate in the SCRO committee's initial or continuing review of any project in which the member has a ~~conflicting interest~~ professional or financial stake, except to provide information to the IRB.

(b) The designated SCRO committee shall provide scientific and ethical review of CIRM-funded research consistent with the requirements of Section 100070 and other applicable CIRM requirements.

(c) The SCRO committee shall facilitate education of investigators with applicable requirements of this chapter.

(d) A~~n~~ SCRO committee may provide oversight for two or more funded research institutions, provided the SCRO committee has oversight authority consistent with the requirements of this chapter.

(e) A~~n~~ SCRO committee may be convened by an institution, a group of institutions, the

CIRM or other state agency.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100070 to read:

§ 100070. SCRO Committee Review and Notification. ~~[Recommended Revisions]~~

(a) CIRM-funded research involving the procurement or ~~derivation of covered stem cell lines or~~ use of human oocytes ~~or embryos in stem cell research~~ may not commence without SCRO committee review and approval in writing. For such SCRO committee review and approval, the member of the committee with expertise in assisted reproduction shall be present. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (a)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to ~~derive a new human stem cell line~~use oocytes ~~or embryos~~. ~~When such research involves the use of oocytes and embryos,~~including a justification for the number needed ~~for derivation shall be provided~~. If SCNT is proposed ~~as a route to generating human stem cell lines,~~a justification for SCNT shall be provided.

(2) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.

(3) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC), Institutional Bioethics Committee (IBC), or other mandated review.

~~(4) DdDocument how resulting stem cell lines will be characterized, validated, stored, and distributed to ensure that the confidentiality of the donor(s) is protected.~~

~~(covered in (c)).~~

(b) CIRM-funded research involving use of human embryos may not commence without SCRO committee review and approval in writing. For such SCRO committee review and approval, the member of the committee with expertise in assisted reproduction shall be present. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (b)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to use embryos including a justification for the number needed. ~~[Note deleted SCNT from here]~~

(2) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.

(3) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC), Institutional Bioethics Committee (IBC), or other mandated review.

~~(4) Document how resulting stem cell lines will be characterized, validated, stored, and distributed to ensure that the confidentiality of the donor(s) is protected. (covered in (c)).~~

(c) CIRM-funded research ~~intended~~ with the aim to derive or create a covered stem cell line may not commence without SCRO committee review and approval in writing. The

designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (c)(~~3~~4) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to derive a covered stem cell line.

(2) If SCNT is proposed as a route to generating human stem cell lines, a justification for SCNT shall be provided.

(~~2~~3) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.

(~~3~~4) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Bioethics Committee (IBC), or other mandated review.

(~~4~~5) Document how stem cell lines will be characterized, validated, stored, and distributed to ensure that the confidentiality of the donor(s) is protected.

(d) CIRM-funded purely in vitro research utilizing covered stem cell lines may not commence without written notification to the designated SCRO committee. At a minimum, the notification shall:

(1) Provide assurance that all covered stem cell lines have been acceptably derived.

(2) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

(e) CIRM-funded research introducing covered stem cell lines into non-human animals or introducing neural-progenitor cells into the brain of non-human animals at any state of embryonic, fetal, or postnatal development may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (e)(3) of this regulation as a condition of granting its approval. The SCRO committee may establish guidelines and procedures for expedited review of animal research so that review by the entire SCRO committee is not required. At a minimum, the SCRO c~~C~~ommittee shall require the investigator to:

(1) Provide assurance that all covered stem cell lines have been acceptably derived.

(2) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the ~~human or n~~nonhuman animal tissues.

(3) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

~~The SCRO may establish guidelines and procedures for expedited review of animal research so that review by the entire SCRO is not required.~~

(f) CIRM-funded research introducing stem cells from covered stem cell lines into a live

born human ~~or non-human animals at any state of embryonic, fetal, or postnatal development~~ may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (f)(4) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale introducing stem cells into humans.

(~~1~~2) Provide assurance that all covered stem cell lines have been acceptably derived.

(~~2~~3) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the human or nonhuman animal tissues.

(~~3~~4) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

~~(c) CIRM-funded purely in vitro research utilizing covered stem cell lines may not commence without written notification to the designated SCRO Committee. At a minimum, the notification shall:~~

~~(1) Provide assurance that all covered stem cell lines have been acceptably derived.~~

~~(2) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.~~

(g) Investigators are entitled to reconsideration of a~~n~~ SCRO committee decision.

Requests must be made in writing and include a summary of the basis for the reconsideration. Investigators are entitled to be present in order to provide information and responses during the reconsideration.

(h) SCRO committee approvals shall be reviewed no less frequently than once per year. The renewal review shall confirm compliance with all applicable rules and regulations. The SCRO committee may establish guidelines and procedures for expedited review of renewals so that review by the entire SCRO committee is not required.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.40, 124290.55, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100080 to read:

§ 100080. Acceptable Research Materials.

All covered stem cell lines used in CIRM-funded research must be "acceptably derived." To be "acceptably derived," the stem cell line must:

(a) Have been approved by the National Institutes of Health, or

(b) Been deposited in the United Kingdom Stem Cell Bank, or

(c) Been derived by, or approved for use by, a licensee of the United Kingdom Human Fertilization and Embryology Authority, or

(d) Been derived in accordance with the Canadian Institutes of Health Research Guidelines for Human Pluripotent Stem Cell Research under an application approved by the National Stem Cell Oversight Committee, or

(e) Have been derived under the following conditions:

(1) Donors of gametes, embryos, somatic cells or human tissue gave voluntary and informed consent.

(2) Donors of gametes, embryos, somatic cells or human tissue did not receive valuable consideration. This provision does not prohibit reimbursement for permissible expenses as determined by an IRB;

(3) A person may not knowingly, for valuable consideration, purchase or sell gametes, embryos, somatic cells, or human tissue for research purposes pursuant to this chapter, ~~except for donors as provided in subdivision (e)(2) of this regulation~~. This provision does not prohibit reimbursement for permissible expenditures as approved by a SCRO committee or IRB, or permissible expenses as determined by an IRB.

"Permissible expenditures" means necessary and reasonable costs directly incurred as a result of persons, not including human subjects or donors, providing gametes, embryos, somatic cells, or human tissue for research purposes. Permissible expenditures may include but are not limited to costs associated with processing, quality control, storage, or transportation of materials.

(4) Donation of gametes, embryos, somatic cells or human tissue was overseen by an IRB (or, in the case of foreign sources, an IRB-equivalent);

(5) Individuals who consented to donate stored gametes, embryos, somatic cells or human tissue were not reimbursed for the cost of storage prior to the decision to donate.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, 125300, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100090 to read:

~~**§ 100090. Additional Requirements for CIRM-Funded Derivation.**~~

~~Where CIRM funds are to be used to derive new human stem cell lines, in addition to the requirements of 17 Cal. Code Regs section 100080, subdivision (e), the SCRO must confirm that the following additional requirements have been met:~~

~~(a) Donors of gametes, embryos, somatic cells or human tissue have given voluntary and informed consent in accordance with17 Cal. Code Regs section section 100100;~~

~~(b) When procurement of oocytes are required for derivation, the following conditions have been met:~~

~~(1) For a woman providing oocytes for research and clinical infertility treatment (either for herself or another woman), research shall not compromise the optimal reproductive success of the woman in infertility treatment~~

~~(2) The funded institution has agreed to assume the cost of any medical care required as a direct and proximate result of oocyte donation for research~~

~~(3) The physician attending to any donor and the principal investigator shall not be the same person unless exceptional circumstances exist and an IRB has approved an exemption from this requirement.~~

~~(4) The physician performing oocyte retrieval shall not have a financial interest in the outcome of the research.~~

~~Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.~~

~~Adopt 17 Cal. Code of Regs. section 100090 to read:~~

§ 100090. Additional Requirements for CIRM-Funded Derivation.

Where CIRM funds are to be used to derive new human stem cell lines after the effective date of this Chapter, in addition to the requirements of 17 California~~.~~ Code of Regulations section 100080, subdivision (e), the SCRO committee must confirm that d~~the following additional requirements have been met:~~

~~(a)~~ Ddonors of gametes, embryos, somatic cells or human tissue have given voluntary and informed consent in accordance with Title17 California~~.~~ Code of Regulations section ~~section~~ 100100.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

§ 100095. Additional Requirements for CIRM-Funded Research Involving Oocytes.

~~(b~~a~~)~~ When procurement of oocytes are required for derivation CIRM-funded research, the SCRO committee must confirm the following conditions have been met:

(a~~1~~) The clinic performing oocyte retrieval is a member of the Society for Assisted Reproductive Technology.

~~(1) For a woman providing oocytes for research and clinical infertility treatment (either for herself or another woman), research shall not compromise the optimal reproductive success of the woman in infertility treatment~~

(b~~2~~) For a woman providing oocytes for research and clinical infertility treatment (either for herself or another woman), the disposition of such oocytes shall not knowingly compromise the optimal reproductive success of the woman in infertility treatment.

(1) ~~(A)~~ A woman providing oocytes for her own reproductive uses may not donate any eggs to research unless she has determined that she does not want or need them to optimize her own chances for reproductive success.

(2~~B~~) A woman providing oocytes for donation to another person's reproductive efforts may not donate any of these eggs to research unless (a) the donation is expressly permitted by the recipient who is receiving her oocytes for reproduction and (b) her donation of oocytes for research is done without valuable consideration.

~~(2) The funded institution has agreed to assume the cost of any medical care required as a direct and proximate result of oocyte donation for research~~

(c~~3~~) The CIRM-funded institution shall develop procedures to ensure that an individual who donates oocytes for CIRM-funded research has access to medical care that is required as a direct and proximate result of that donation at no cost to the donor.

(d~~34~~) The physician attending to any donor and the principal investigator shall not be the same person unless exceptional circumstances exist and an IRB has approved an exemption from this requirement.

(e~~45~~) The physician performing oocyte retrieval shall not have a financial interest in the outcome of the research.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

~~Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.~~

Adopt 17 Cal. Code of Regs. section 100100 to read:

§ 100100. Informed Consent Requirements.

(a) All CIRM-funded human subjects research shall be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (Protection of Human Subjects), revised June 23, 2005, and California Health and Safety Code section 24173. In accordance with existing law, California Health and Safety Code section 24173 does not apply to a person who is conducting research as an investigator within an institution that holds an assurance with the United States Department of Health and Human Services pursuant to Title 45 Code of Federal Regulations Part 46, revised June 23, 2005, and who obtains informed consent in the method and manner required by those regulations.

(b) CIRM-funds may not be used for research that violates the documented preferences of donors with regard to the use of their donated materials. To ensure donors are fully informed of the potential uses of donated materials, researchers shall disclose, in addition to the general requirements for obtaining informed consent, all of the following, unless a specific item has been determined by the SCRO committee or IRB to be inapplicable.

(1) Derived cells or cell products may be kept for many years.

(2) Whether the identity(ies) of the donor(s) will be ascertainable to those who work with the resulting cells or cell products. If the identity(ies) of the donor(s) are retained (even coded), CIRM-funded researchers must discuss any plans for recontact of donors of materials used to derive cell lines and obtain consent for recontact. This requirement includes both recontacting donors to provide information about research

findings and recontacting donors to ask for additional health information. Donors may be recontacted in the future only if they consent to recontact at the time of donation.

(3) Researchers may use cell lines for future studies, some of which may not be predictable at this time.

(4) Derived cells or cell products may be used in research involving genetic manipulation.

(5) Derived cells or cell products may be transplanted into humans or animals.

(6) Derived cells or cell products are not intended to provide direct medical benefit to the donor(s), except in the case of autologous donation.

(7) The donation is being made without restriction regarding who may be the recipient of transplanted cells, except in the case of autologous donations.

(8) That neither consenting nor refusing to donate materials for research will affect the quality of any future care provided to potential donors.

(9) That the results of research may be patentable or have commercial potential, and that the donor will not receive patent rights and will not receive financial or any other benefits from future commercial development.

(c) Researchers shall offer donors an opportunity to document their preferences regarding future uses of their donated materials. Researchers may choose to use materials only from donors who agree to all future uses.

(d) For CIRM-funded research involving the donation of oocytes, the following additional requirements apply:

(1) The description of foreseeable risk shall include but not be limited to information regarding the risks of ovarian hyperstimulation syndrome, bleeding, infection, anesthesia and pregnancy.

(2) The physician must disclose his or her relationship to the research or researcher(s) to the egg donor.

~~(3) Steps shall be taken to enhance the informed consent process. Measures to do so shall include, but are not limited to, an adequate period of time, as determined by an IRB, to deliberate about the decision to donate. In the case of such periods of deliberation, researchers may not solicit potential donors until they have initiated recontact with the researchers~~

(3) Prospective donors shall be informed of their option to deliberate before deciding whether or not to give consent. If a deliberation period is chosen, the researchers may not ~~solicit~~ re-contact the prospective donor about the consent decision.

(4) The researcher shall ascertain that the donor has understood the essential aspects of the research,~~.~~ ~~Researchers may meet this requirement by following a process that is approved by the designated Institutional Review Board or SCRO committee. Researchers must~~ following a process approved by the designated IRB ~~and~~or SCRO c~~C~~ommittee. Understanding the essential aspects of the research includes understanding at least that:

(A~~i~~)~~.~~ Their eggs will not be used for reproductive purposes.

(B~~ii~~)~~.~~ There are medical risks in oocyte donation, including the risks of ovarian hyperstimulation syndrome, bleeding, infection, anesthesia, and pregnancy.

(C~~iii~~). The research will not benefit them or any other individuals directly at this time.

(D~~iv~~). Whether stem cell lines will be derived from their oocytes through fertilization, SCNT, parthenogenesis, or some other method.

(E~~v~~). Stem cell lines developed from their oocytes will be grown in the lab and shared with other researchers for studies in the future.

(F~~vi~~). If stem cells are to be transplanted into patients, researchers might recontact the donor to get additional health information.

(G~~vii~~). Donors receive no payment beyond reimbursement for permissible expenses.

(H~~viii~~). Stem cell lines derived as a result of their oocyte donation may be patented or commercialized, but donors will not share in patent rights or in any revenue or profit from the patents.

(e) For CIRM-funded research involving the donation of embryos for stem cell research, the informed consent process shall include a statement that embryos will be destroyed in the process of deriving embryonic stem cells.

~~(f) For CIRM-funded research involving the donation of the umbilical cord, cord blood or the placenta, consent shall be obtained from each known legal parent, guardian or progenitor. Informed consent shall include a statement as to whether the donated cells may be available for autologous treatment in the future.~~

(f) For CIRM-funded research that uses umbilical cord, cord blood or the placenta for autologous donation or for purposes other than derivation of covered stem cell lines, consent shall be obtained from the woman giving birth. –For CIRM-funded research that uses umbilical cord, cord blood or the placenta to derive covered stem cell lines for purposes other than autologous donation, in order to assure scientific rigor, consent shall be obtained from each legal parent, guardian and genetic parent. Nothing in this section shall be construed to affect state or federal law with regard to consent in reproductive decision making.

(g) For purposes of this regulation, "genetic parent" means the person who provided the sperm or ovum for fertilization.

(~~g~~h) For CIRM-funded research involving the donation of somatic cells for SCNT, informed consent shall include a statement as to whether the donated cells may be available for autologous treatment in the future.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 24173, 125290.35, 125290.40, 124290.55, 125315, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100110 to read:

§ 100110. Fairness and Diversity in Research.

CIRM grantees shall comply with the California Health Research Fairness Act, California Health and Safety Code, Sections 439.900-439.906, and Inclusion of Women and Minorities in Clinical Research Act, Health and Safety Code, Sections 100237-100239.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 439.900-439.906, 100237-100239, 125290.40, 124290.55, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100120 to read:

§ 100120. Record Keeping.

Each grantee's institution shall maintain records of all CIRM-funded research activities. At a minimum, the institution shall maintain a research registry that includes, but is not limited to, documentation of:

(a) CIRM-funded stem cell research conducted by the institution;

(b) Any required review or notification requirements as described in 17 Cal. Code of Reg.s section 100070;

(c) The methods utilized to characterize and screen the materials for safety;

(d) The conditions under which the materials have been maintained and stored;

(e) Any additional requirements set forth in any other regulations under this title;

(f) Every gamete, somatic cell, embryo donation or product of SCNT that has been donated, created or used. This record should be sufficient to determine the provenance and disposition of such materials.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100130 to read:

§ 100130. Materials Sharing.

Stem cell lines and biomedical materials developed with CIRM funding at academic, commercial research and development organizations shall be broadly disseminated. CIRM-funded research institutions shall comply with any CIRM-Intellectual Property regulations intended to ensure data and materials sharing.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.30, subd.(h), 125290.40, 124290.55, Health and Safety Code.